Notice of Allowability	Application No.	Applicant(s)	
	10/631,143	PEYMAN, GHOLAM	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *09 January 2006*.

2. ☒ The allowed claim(s) is/are *6,10-12,15,17,20,22,25,37 and 38*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 01/09/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *03/03/06* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Humera N. Sheikh
HUMERA N. SHEIKH
PATENT EXAMINER
TC-1600

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114, the Amendment, Applicant's Arguments/Remarks and the Information Disclosure Statement (IDS), all filed 01/09/06 is acknowledged.

Claims 6, 10-12, 15, 17, 20, 22, 25, 37 and 38 are pending in this application. Claims 6, 10, 11, 15, 20, 25 and 37 have been amended. Claims 1-5, 7-9, 13, 14, 16, 18, 19, 21, 23, 24, 26-36, 39 and 40 have been cancelled. Claims 6, 10-12, 15, 17, 20, 22, 25, 37 and 38 are allowed.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/09/06 has been entered.

Information Disclosure Statement

In the Information Disclosure Statement (IDS) filed 01/09/06, the reference documents on page 1 which have been crossed off by the Examiner, have been considered and made of record by the Examiner, however, the crossed off reference documents will not be printed on the face of the patent publication. The references are missing appropriate dates.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Beverly A. Lyman on March 03, 2006.

The application has been amended as follows:

In the Claims :

In claim **6**, last line, the limitation "**or intraocular implantation**" has been **deleted**.

In claim **15**, line 6, the limitation "**or intraocular implantation**" has been **deleted**.

In claim **20**, line 6, the limitation "**or intraocular implantation**" has been **deleted**.

In claim **25**, line 8, the limitation "**or intraocular implantation**" has been **deleted**.

In claim **25**, last line, the blank space between the word 'ml' and the period (.) has been deleted.

Claims **1 and 5** have been **cancelled**.

In the Abstract:

In the first line, the phrase 'Treatment of Ocular Disease' has been deleted.

Allowable Subject Matter

Claims 6, 10-12, 15, 17, 20, 22, 25, 37 and 38 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Robinson *et al.* – U.S. Patent No. 6,713,081 B2; Kulkarni – U.S. Patent No. 5,387,589 & Ueno – U.S. Patent No. 6,872,383) does not disclose nor suggest or teach the instantly claimed method of treating specific posterior segment diseases (diabetic retinopathy, retinitis pigmentosa, age related macular degeneration) by intraocularly administering by intraocular injection a rapamycin- or ascomycin- containing (and combinations thereof) composition, whereby the drug is provided at a concentration up to about 200 μg/ml, effective to treat the posterior segment disease (diabetic retinopathy, retinitis pigmentosa, age related macular degeneration). The prior art does not disclose nor suggest or teach administering a rapamycin or ascomycin-containing (and combinations thereof) composition by intraocularly injecting the composition in the eye of a patient to treat diseases (diabetic retinopathy, retinitis pigmentosa, age related macular degeneration) in the back of the eye. The instant invention provides for anterior administration of drug (rapamycin/ascomycin) to treat posterior segment diseases of the eye, which is not disclosed or taught by the prior art of record. Applicant's method provides for local administration of rapamycin or ascomycin in non-toxic concentrations (less than 200 μg/ml by intraocular injection), which is not disclosed or taught by the prior art. Applicants have demonstrated that these amounts are crucial, since

rapamycin and ascomycin are potent immunosuppressant drugs, which must be administered in appropriate amounts below the toxic concentration levels.

In contrast, the prior art (Robinson *et al.* '081) discloses implants with 2-methoxyestradiol or angiogenic compounds as therapeutic agents to treat age related macular degeneration, but does not disclose or teach the use of rapamycin and/or ascomycin (or combinations thereof) to treat posterior segment diseases such as diabetic retinopathy, retinitis pigmentosa or age related macular degeneration, whereby the drug is intraocularly injected into the eye. The references of Kulkarni ('589) and Ueno ('383) further do not remedy the deficiencies of Robinson ('081) and do not disclose nor teach the treatment of posterior segment diseases through anterior segment routes of administration, such as by intraocular injection, as instantly claimed.

The instant invention demonstrates an improvement over prior art formulations because it provides for the effective treatment of posterior segment diseases by administering drug (rapamycin and/or ascomycin) to the anterior segment of the eye. The instant method provides for the local administration of rapamycin and/or ascomycin, which are very potent drugs, in non-toxic concentrations (less than 200 g/ml by intraocular injection). The instant invention provides for long-term treatment of chronic diseases and avoids systemic administration of drug.

Hence, in view of the improvements of the present invention and the lack of teachings of the instant limitations by the prior art, the instant invention is rendered non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh Humera N. Sheikh
Patent Examiner TC-1600
Art Unit 1615
February 27, 2006

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